REMARKS

Claims 1 – 19 are pending, with claims 18 and 19 being newly added. In the Office Action, the Examiner issued a restriction requirement under 35 U.S.C. §§ 121 and 372. In the restriction, the Examiner separated the claims into the following two groups: Group I, said to be drawn to an antibiotic composition (Claims 1 – 13), and Group II, said to be drawn to a method of preparing an antibiotic composition (Claims 14-17). The Office Action asserts that the claims of Group I and the claims of Group II are not so linked as to form a single general inventive concept under PCT Rule 13.1. Applicants respectfully disagree with and traverse this conclusion, and assert that the Examiner has failed to make out sufficient grounds under the law to support restriction of the claims in this case. They simply are not that different.

Notwithstanding the manifest error in the restriction imposed in this case, Applicants will, for purposes of advancing prosecution, provisionally elect the Group I claims (Claims 1-14), but this election is made, as indicated above, with traverse and under protest. Again, Applicants believe the restriction is not in accord with either § 121 or § 372, as described in more detail below. Applicants also note the above amendments to Claims 13, 14, and 15, and the addition of new dependent claims 18 and 19, all made for the purpose of clarifying the subject matter of the claims, and to help make it even more clear that restriction of the claims is not warranted.

In light of the foregoing amendments and the following remarks, reconsideration of the restriction and withdrawal of the same is respectfully requested.

Restriction requirement Under § 372

As a preliminary matter, Applicants note that claim 14 was mistakenly put into Group II with the method claims. However, claim 14 is dependent on claim 13, a composition of matter claim, and specifies (as amended) that the liquid medium called for in claim 13 is an aqueous medium. Claim 14 is plainly not a method claim. It belongs in Group I, not Group II.

Although the restriction is not believed to be proper, and Applicants are hopeful it will be withdrawn, in the event it is maintained, Applicants expect the Examiner will at least recognize that Groups I and II should be reconstituted as Group I, with claims 1-14, and Group II, with claims 15-19.[1]

1 New claims 18 and 19 would go into Group II for purposes of discussion.

In light of this possibility and reconstituting of Groups I and II, Applicants have provisionally elected Group I comprised of claims 1-14, as indicated above. Again, this election is with traverse.

PCT Rule 13.2 states, *inter alia*, "the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Rule 13.2 further defines a "special technical feature" as "those technical **features** [--note the use of the *plural* form of the term "features"--] that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art" (emphasis and comments added).

With regard to the segregation of the Group I claims from the Group II claims, a basis for restriction of the same is plainly not made out here. According to 37 CFR § 1.475 (b) (1), claim groups in a PCT national stage application drawn to "different categories of invention" are said to have sufficient unity for examination purposes when they are related as "***a product and a process specially adapted for the manufacture of the product,***" unless such claims are shown to lack a "special technical feature." In this case, it is quite evident that the Group II method claims embody methods that could be used to make products and compositions as called for in the Group I claims.[2]

The alleged basis for lack of unity between the Group I and Group II claims is said to be that the method claims call for excipients, while the composition claims do not. However, it is evident the "one or more excipients" mentioned in claim 15, as originally submitted, are "optional." Also, Applicants have put forward an amendment to clarify claim 13 in regard to the optionality of combining the one ore more antibiotics with one or more excipients and have added a new dependent claim 18, which explicitly calls for a "premix" that includes the one or more antibiotic mixed with at least one or more excipients.

It should now be even more evident that independent method claim 15 does not require the presence of one or more excipients in combination with, among other things, one or more antibiotics, although the mixing of one or more antibiotics with one or more excipients is certainly a preferred embodiment, which is now specified in new claim 18 to form the "premix" for being combined with a solvent as claimed.

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2 Of course, this is with the exception of Claim 14, which is a composition of matter claim dependent on composition Claim 13, erroneously put in Group II with the method claims.

Hence, the premise of the restriction, i.e., that claim 15 required excipients, while believed to have been inaccurate, has been clearly obviated by the amendment to claim 15 and the adding of new claim 18, which under the doctrine of "claim differentiation" would make it even more plain that one or more excipients are not required in the practice of the full scope of the method of claim 15.

Accordingly, Applicants submit that claims 1 and 13, on the one hand, and claim 15, on the other (taking into account their dependent claims as well), are related under Rule 1.475(b)(1) as products/compositions and methods specially adapted to make such products/compositions.

Furthermore, the mere pointing out that the method claims call for excipients not "found" in the composition, while inaccurate, does not even arguably demonstrate that independent method claim 15 and the independent product/composition claims lack a common or corresponding "special technical feature." The claims have enough in common including, but not limited to, the requirement of specially coated antibiotic-containing micropellets in a defined size range of from about 100 to about 650 μm, to make it evident they meet the unity requirements of at least Rule 1.475 and of any other applicable rules and/or regulations.

Thus, under Rule 1.475(b) (1), it is evident that the Group I claims and the Group II claims have not been shown to lack unity. Therefore, Applicants respectfully submit that no basis has been made out under Rule 1.475 or otherwise to require Applicants to elect as between the claims contained in Group I and Group II. The restriction is not well taken and should be withdrawn. All pending claims should be examined together.

Finally, as mentioned above, the Examiner has failed to carry his burden of specifically describing how the claims of Group I and the claims of Group II lack a common or corresponding "special technical feature." Rather, the Examiner has merely stated that "additional excipients" are mentioned in the method claims which, as discussed above, misses the mark. "When making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) ***specifically describing the unique special technical feature in each group***." M.P.E.P. § 1893.03(d) (emphasis added). Merely mentioning that one group of claims calls for "additional excipients," even if a correct observation (and it is not), fails to satisfy this requirement. Conclusary allegations do not suffice, and it is not Applicants' burden to demonstrate the existence of a common or corresponding "special technical feature" in the claims

in question. Requiring an Applicant to do so at this stage of a case would turn the Patent Act on its head.

Having failed to explain how the claims lack a common or corresponding special technical feature or how they otherwise lack unity for purposes of examination, the Examiner's burden to make at least a *prima facie* case in support of the restriction has not been met. Accordingly, for this additional reason, the restriction requirement cannot properly be maintained, and the same should be withdrawn and all claims examined together.

For the reasons stated above, Applicants respectfully request the Examiner reconsider and withdraw the restriction requirement, and such action is respectfully solicited.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12-2355.**

Respectfully submitted,

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